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United States District Court
Central District of California

JORDAN EISMAN,

Plaintiff,

v.

JOHNSON & JOHNSON CONSUMER, INC. et al.,

Defendants.

Case № 2:24-cv-01982-ODW (AJRx)

ORDER GRANTING MOTION TO DISMISS [18]

I. INTRODUCTION

Plaintiff Jordan Eisman brings this putative class action against Defendants Johnson & Johnson Consumer, Inc. and Kenvue, Inc., asserting causes of action for fraud, breach of warranties, and violation of consumer protection laws, based on the undisclosed presence of benzene in two of Defendants' Neutrogena T/Gel Therapeutic Shampoos (the "Products"). (Compl. ¶¶ 1, 43–133, ECF No. 1.) Defendants move to dismiss Eisman's claims pursuant to Federal Rules of Civil Procedure ("Rule" or "Rules") 12(b)(1) and 12(b)(6). (Mot. Dismiss ("Motion" or "Mot."), ECF No. 18.) For the reasons below, the Court **GRANTS** the Motion.[1]

[1] Having carefully considered the papers filed in connection with the Motion, the Court deemed the matter appropriate for decision without oral argument. Fed. R. Civ. P. 78; C.D. Cal. L.R. 7-15.

II. BACKGROUND[2]

Defendants manufacture, sell, market, and distribute the Products in the United States as an over-the-counter ("OTC") nonprescription treatment for scalp conditions. (Compl. ¶¶ 3–4, 7–8; Opp'n 1, ECF No. 41.) The active ingredient in the Products is Coal Tar, a complex compound comprised of "as many as 10,000" naturally occurring constituent components. (Compl. ¶¶ 1, 16–17.) Benzene is one of the constituent components of Coal Tar. (*Id.* ¶ 17.)

Eisman is a citizen of California who purchased Neutrogena T/Gel Therapeutic Shampoo—Extra Strength in February 2021. (*Id.* ¶ 6.) Eisman recently discovered through "testing" that the Products contain "dangerously high, undisclosed levels of benzene, a hazardous genotoxic substance." (*Id.* ¶¶ 2, 22.) Benzene is typically used in the manufacture of gasoline, industry chemicals, and textiles. (*Id.* ¶ 3.) It is known to be a human carcinogen, and is "associated with numerous side effects." (*Id.* ¶ 14.)

Eisman claims that the undisclosed presence of benzene renders Defendants' representations that the Products are "safe and effective" false and misleading. (*Id.* ¶¶ 1–5; *see, e.g.*, *id.* ¶ 46.) He also asserts that the undisclosed presence of benzene means the Products are improperly manufactured, tested, marketed, packaged, and labeled, because Defendants were obligated to remove all traces of benzene during the manufacturing process. (*See id.* ¶¶ 1–5, 20.) Eisman claims he would not have paid money for the Products had he known of the presence of benzene. (*Id.* ¶ 6.)

Based on the above allegations, Eisman filed this putative class action against Defendants. He asserts seven causes of action based on the undisclosed presence of benzene in the Products: (1) breach of express warranties; (2) breach of implied warranties; (3) fraud (affirmative misrepresentation, omission, and concealment); (4) negligent misrepresentation and omission; (5) violation of the consumer protection laws of all states; (6) negligence; and (7) unjust enrichment. (*Id.* ¶¶ 43–133.) Eisman

[2] All factual references derive from Eisman's Complaint, unless otherwise noted, and well-pleaded factual allegations are accepted as true for purposes of this Motion. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

seeks economic damages, declaratory relief, and "appropriate . . . injunctive relief." (*Id.*, Prayer.) Eisman does not seek to recover for physical injuries, but he alleges "physical," "undisclosed sub-cellular or structural impact" to his body. (*Id.* ¶ 71.)

Defendants move to dismiss Eisman's claims pursuant to Rules 12(b)(1) and 12(b)(6), raising grounds for dismissal including federal preemption, lack of Article III standing, collateral estoppel, and failure to state a claim. (Mot. 1–4, 13.)[3] As the Court agrees with Defendants that Eisman's claims are expressly preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, the Court declines to reach Defendants' additional arguments for dismissal.

III. LEGAL STANDARD

A court may dismiss a complaint under Rule 12(b)(6) for lack of a cognizable legal theory or insufficient facts pleaded to support an otherwise cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). To survive a dismissal motion, a complaint need only satisfy the minimal notice pleading requirements of Rule 8(a)(2)—a short and plain statement of the claim. *Porter v. Jones*, 319 F.3d 483, 494 (9th Cir. 2003). The factual "allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). That is, the complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted).

The determination of whether a complaint satisfies the plausibility standard is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. A court is generally limited to the pleadings and must construe all "factual allegations set forth in the complaint . . . as true and . . . in the light most favorable" to the plaintiff. *Lee v. City of Los Angeles*, 250 F.3d 668, 679 (9th Cir. 2001). However, a court need not blindly accept

[3] The parties request that the Court take judicial notice of certain documents. (Defs. Req. Judicial Notice ("RJN") Exs. A–E, ECF No. 19; Pl. RJN Exs. A–B, ECF No. 43.) As the Court resolves the Motion without relying on the documents, it denies the requests.

conclusory allegations, unwarranted deductions of fact, and unreasonable inferences. *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001).

IV. DISCUSSION

Defendants argue Eisman's claims are expressly preempted by the FDCA and the Food and Drug Administration's ("FDA") regulations promulgated thereunder. (Mot. 3.) Specifically, Defendants cite 21 U.S.C. § 379r(a), which prohibits states from "establish[ing] or continu[ing] in effect any requirement . . . that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]." 21 U.S.C. § 379r(a)–(c)(2). Defendants contend Eisman seeks to use state laws to force Defendants to include disclosures and comply with conditions that are different from and additional to those that the FDA requires in the applicable OTC Coal Tar drug product monograph. (Mot. 3 (citing 21 C.F.R. § 358.701 *et seq.*).)

A. Express Preemption—FDCA, 21 U.S.C. § 379r

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). However, federal preemption of state law "will not lie unless it is the clear and manifest purpose of Congress." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, (1993) (internal quotation marks omitted). If a federal statute contains an express preemption clause, the court "focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Puerto Rico v. Franklin Cal. Tax-Free Tr*, 579 U.S. 115, 125 (2016) (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 594 (2011)).

To ensure uniformity in the regulation of OTC drugs, like Defendants' Products, the FDCA contains a broad express preemption provision: 21 U.S.C. § 379r. That provision generally prohibits states from establishing "any requirement . . . (1) that relates to the regulation of a [nonprescription drug]; and (2) that is *different from or in addition to, or that is otherwise not identical with*, a requirement under [the FDCA]." *Id.* § 379r(a) (emphasis added). The statute defines "requirement" to include "any

requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug." *Id.* § 379r(c)(2).

The Supreme Court has recognized that the FDA alone can balance "the potentially competing concerns of safety and effectiveness," meaning that "common law and state law liability that is also premised on a product's safety and effectiveness can only upset that balance." *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1281 (C.D. Cal. 2008) (discussing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324–25 (2008)). In the context of 21 U.S.C. § 379r, this means that "virtually any state requirement that relates to the regulation of nonprescription drugs can be preempted, regardless of the common law theory under which it is brought." *Id.* at 1282. "Simply stated, federal law expressly preempts any state law that applies to OTC drugs and purports to impose additional or different requirements than the requirements set forth by the FDA." *Faustino v. Alcon Lab'ys, Inc.*, No. 2:15-cv-04145-RGK (AJWx), 2015 WL 12839161, at *2 (C.D. Cal. Sept. 22, 2015), *aff'd sub nom. Faustino v. Alcon Lab'ys, Inc. (a Division of Novartis AG)*, 692 F. App'x 819 (9th Cir. 2017).

In contrast, 21 U.S.C. § 379r does not preempt claims under state law that impose identical or "parallel" requirements to FDA regulations, such as where a plaintiff sues over a defendant's violation of the FDCA. *Riegel*, 552 U.S. at 330; *Seale v. GSK Consumer Health, Inc.*, 718 F. Supp. 3d 1208, 1223 n.6 (C.D. Cal. 2024) ("[F]ederal preemption does not necessarily apply where certain common law claims and remedies are parallel or equivalent to federal regulations.").

B. OTC Coal Tar Monograph

The FDA regulates OTC Coal Tar drugs such as the Products via a comprehensive set of FDA regulations called a monograph. 21 C.F.R. §§ 330.1, 358.701. The FDA promulgated its monograph for OTC Coal Tar drug products after an extensive review process involving the recommendations of an expert advisory panel and public notice and comment. *See id.* § 330.10.

The OTC Coal Tar drug product monograph specifies, among other things, the permissible active ingredients and their concentrations and combinations, as well as indications for use, warnings, directions, and other mandatory labeling requirements. *See id.* §§ 358.701, 358.703, 358.710, 358.720, 358.750, 358.760. In particular, the monograph expressly permits Coal Tar to be an active ingredient in the Products in specified amounts. *Id.* §§ 358.703, 358.710(a)(1). It also provides detailed instructions for labeling covered products, including specific warnings and directions that must be included for OTC drug products containing Coal Tar. *See id.* § 358.750.

The regulations provide that an OTC Coal Tar drug product "is generally recognized as safe and effective and is not misbranded if it meets each of the conditions" in the monograph and "each general condition" in 21 C.F.R. § 330.1. *Id.* § 358.701(a). Section 330.1, in turn, specifies that OTC drugs must meet the conditions described therein concerning manufacture, labeling, dosage, containers, and language permitted and prohibited. *Id.* § 330.1(c)(1). Any product that fails to comply with these requirements is subject to regulatory action as "adulterated" or "misbranded," and prohibited from sale. *See id.*; 21 U.S.C. §§ 331, 351 (adulterated), 352 (misbranded).

As Defendants' Products contain Coal Tar, (*see* Compl. ¶ 1), they are regulated by the OTC Coal Tar drug product monograph and subject to "requirement[s] under [the FDCA]," 21 U.S.C. § 379r(a).

C. Analysis

The Court agrees with Defendants that 21 U.S.C. § 379r(a) preempts Eisman's claims regarding the Products. Eisman broadly premises each of his causes of action on allegations that Defendants misrepresented the Products via statements in the "labeling and packaging that described the [P]roduct[s] as safe and effective without disclosing the presence or levels of benzene." (Compl. ¶¶ 47 (breach express warranties), 60 (breach implied warranties), 76 (fraud), 92 (negligent misrepresentation/omission), 108 (violation consumer protection laws); *see id.* ¶¶ 119

(negligence), 129 (unjust enrichment).) Eisman alleges that, consequently, "the [P]roduct[s] w[ere] not manufactured, tested, or marketed properly to account for undisclosed impurities, substances, or risks." (*Id.* ¶¶ 48; *see id.* ¶¶ 60, 75–76, 92, 107–08, 111, 119, 129.)

As Eisman does not identify any specific statement or representation on which he relied, his allegations make clear that he premises his claims primarily on an omission theory, and secondarily on an adulterated and misbranded product theory. (*See id.* ¶¶ 1–6, 48, 60, 75–76, 92, 107–08, 111, 119, 129.) Whether Eisman's theory of liability is that the presence of benzene requires a disclosure that Defendants omit, or that it renders the Products adulterated and misbranded, each of his claims seeks to impose requirements that are "different from or in addition to, or that [are] otherwise not identical with" the FDA's. 21 U.S.C. § 379r(a).

1. Disclosure or Warning

Eisman claims that Defendants fraudulently and negligently misrepresented the Products as safe and effective without disclosing the presence of a harmful substance, i.e., benzene. (Compl. ¶¶ 1–5, 13–23, 46–48, 60–61, 75–76, 92, 107–08, 119, 129.) Under this omission theory, Eisman essentially seeks to force Defendants to add a disclosure or warning about benzene to the label of its Products. But the FDA's monograph for OTC Coal Tar drug products already regulates the labeling of the Products, and the monograph requires neither the disclosure nor the warning that Eisman seeks. *See* 21 C.F.R. § 358.701 *et seq.* (OTC Coal Tar drug product monograph). Insofar as Eisman's claims require disclosures in addition to the FDA's labeling requirements, these claims are preempted. *See Seale*, 718 F. Supp. 3d at 1221–22 (finding state law claims preempted where plaintiff sought an antitussive disclosure different from the FDA's applicable monograph); *Faustino*, 2015 WL 12839161, at *2 (finding state law claim preempted where plaintiff sought a warning for eye drops different from or additional to the FDA's regulations).

Moreover, to the extent Eisman may argue that Defendants must include benzene as a component of the Products, the OTC Coal Tar drug monograph requires disclosure of the active and inactive ingredients. 21 C.F.R. §§ 201.66(c) (content requirements), 358.710 (OTC Coal Tar drug products monograph—active ingredients). Benzene does not fit the definition of either active or inactive ingredients, because it is not a purposefully added component of the drug. *See* 21 C.F.R. § 210.3(b)(3) (defining a "component" as "any ingredient *intended* for use in the manufacture of a drug product" (emphasis added)); *id.* §§ 201.66(b)(2) (defining active ingredient), (b)(8) (defining inactive ingredients as "any component other than an active ingredient"); (*see also* Compl. ¶¶ 15–17 (alleging benzene is one of potentially thousands of constituents existing in Coal Tar)). As such, the monograph does not require Defendants to include benzene on the label, and imposing such a requirement would be inconsistent with the FDA's regulations. *See Howard v. Alchemee, LLC*, No. 2:24-cv-01834-SB (BFMx), 2024 WL 4272931, at *8 (C.D. Cal. Sept. 19, 2024) (finding state law claims preempted where they would require defendants to disclose benzene as an ingredient in OTC acne products when the monograph did not require the disclosure), *appeals filed*, Nos. 24-6404, 24-6431, 24-6684 (9th Cir. Nov. 2024).[4]

2. Adulterated or Misbranded

Turning to Eisman's secondary theory, Eisman alleges that the Products are "adulterated" or "misbranded," pursuant to 21 U.S.C. §§ 351 and 352, because benzene is unsafe in any amount. (*See* Compl. ¶ 5; Opp'n 10 ("[B]enzene should not be present in drug products," and "benzene's presence renders a drug unsafe and therefore adulterated or misbranded.").) He contends that Defendants are obligated, but failed to, "properly manufacture their [Products] to . . . eliminate benzene or

[4] Eisman makes a passing suggestion that Defendants should ask the FDA to change the monograph. (Opp'n 11.) However, the Court is not persuaded by Eisman's out of circuit and inapposite authority on this point.

properly test and monitor their [Products] for the presence of benzene."[5] (Compl. ¶¶ 18–20; *see id.* ¶¶ 48, 61, 76, 92, 108, 111, 119, 129; Opp'n 10.) Thus, he argues his claims are parallel to the federal requirements, and not preempted, because he merely seeks to require "Defendants to do that which they already must do under federal law," i.e., eliminate the benzene. (Opp'n 10.)

Eisman's claims are not parallel to the FDCA's bar on the sale of adulterated or misbranded drugs because the relief Eisman seeks—the removal of benzene—is "fundamentally at odds with the FDA's monograph." *Howard*, 2024 WL 4272931, at *7. When the FDA approved the OTC Coal Tar drug product monograph, it did so with full knowledge that Coal Tar contains benzene. *See* Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Over-the-Counter Human use; Tentative Final Monograph, 51 Fed. Reg. 27348 (July 30, 1986) (noting "it is well-established that coal tar contains substances that possess carcinogenic properties"); OTC Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis; Establishment of a Monograph, 47 Fed. Reg. 54656 (Dec. 3, 1982) ("Coal tar consists generally of 2 to 8 percent light oils (*benzene*, toluene, and xylene) . . . .") (emphasis added). Thus, the FDA approved OTC Coal Tar drug products as generally safe and effective, and not adulterated, with the understanding that they would contain some level of benzene.

Moreover, the FDA deems an OTC drug "generally recognized as safe and effective and is not misbranded if it meets each of the conditions" imposed by 21 C.F.R. § 330.1 and the applicable monograph. 21 C.F.R. § 358.701(a); *Seale*, 718 F. Supp. 3d at 1222. Eisman does not argue the Products fail to comply with the monograph or any specific conditions in 21 C.F.R. § 330. (*See generally* Compl.; Opp'n.) Yet he nevertheless asserts "the presence of benzene in the [P]roducts

[5] Although Eisman initially alleged that Defendants must "reduce or eliminate benzene," (Compl. ¶ 18), his arguments in opposition clarify his position that benzene in any amount is unsafe and renders the Products adulterated, (Opp'n 11 (arguing "the Products are not manufactured properly because they contain benzene").)

rendered them 'adulterated and/or misbranded' under federal and parallel state law." (Opp'n 9 (internal citation omitted).) Consequently, Eisman essentially challenges the FDA's determination that OTC drugs "containing [Coal Tar] are 'generally recognized as safe and effective' and 'not misbranded'" if they comply with the monograph and 21 C.F.R. § 330.1. *See Howard*, 2024 WL 4272931, at *7 (finding state law claims preempted and not parallel to federal requirements where plaintiffs argued OTC acne drugs were adulterated because they contained a component known to degrade into benzene); *Seale*, 718 F. Supp. 3d at 1222 (finding state law claims preempted and not parallel to federal requirements where plaintiff argued antitussive products were misbranded because they omitted a disclosure not required by the monograph).

Eisman argues the FDA, in recent industry guidance, declared that "benzene should not be present in drug products," and that this supports that Products containing benzene are "adulterated." (Opp'n 10 (citing Pl. RJN Ex. A ("Reformulating Drug Products that Contain Carbomers Manufactured with Benzene—Guidance for Industry" or "FDA Guidance"), ECF No. 43-1.[6]).) The FDA Guidance provides recommendations specific to "drug products that use carbomers *manufactured with benzene*." (FDA Guidance 1 (emphasis added).) As Eisman alleges benzene is one of thousands of compounds existing within Coal Tar, (Compl. ¶¶ 15–17), the Products are not "manufactured with benzene." The cited FDA Guidance is thus inapplicable as it is directed to an entirely different class of drug products. *See Howard*, 2024 WL 4272931, at *9, n.9 (rejecting similar argument because "Plaintiffs have not alleged that the 'presence of benzene in [the product] stems' from the manufacturing process . . . . On the contrary, they allege that the cause is the inevitable degradation of [the active ingredient]."). Even were the FDA

[6] The Court notes Defendants' objection to judicial notice of the FDA Guidance, (Defs. Opp'n Pl. RJN, ECF No. 46), that as Eisman does not reference the FDA Guidance in his Complaint, he may not introduce new allegations based thereon in opposition to Defendants' Motion. While the Court does not take judicial notice of the FDA Guidance, the Court considers it for the limited purpose of evaluating the propriety of leave to amend. In any event, as discussed herein, the Court finds the FDA Guidance inapplicable.

Guidance applicable to the Products, it is non-binding guidance lacking the force of law. (*See* FDA Guidance 1 ("Contains Nonbinding Recommendations"; "This guidance . . . does not establish any rights for any person and is not binding on FDA or the public.")); *Bowen v. Energizer Holdings, Inc.*, 118 F.4th 1134, 1148 n.12 (9th Cir. 2024) (finding FDA Alert and FDA FAQs lacked the force of federal law and would not be subject to deference by the court). Therefore, the FDA Guidance does not impose on Defendants an obligation to eliminate benzene from the Products, and Eisman's claims seeking to do so are not parallel to federal requirements.

In sum, Eisman impermissibly seeks via his state law claims to impose requirements that are "different from or in addition to, or that [are] otherwise not identical with" the FDCA. 21 U.S.C. § 379r(a)(2). His claims are therefore preempted by federal law and must be dismissed.

D. Leave to Amend

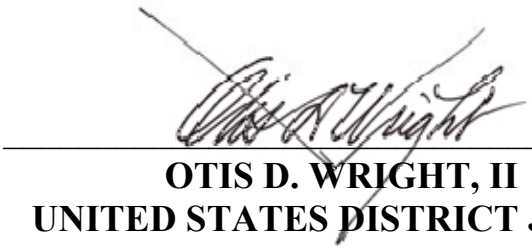
Though courts "should freely give leave [to amend] when justice so requires," Fed. R. Civ. P. 15(a)(2), leave may be denied when "amendment would be futile," *Carrico v. City & County of San Francisco*, 656 F.3d 1002, 1008 (9th Cir. 2011). Preemption generally cannot be cured by amendment. *See Webb v. Trader Joe's Co.*, 999 F.3d 1196, 1205 (9th Cir. 2021) (affirming dismissal with prejudice because plaintiff could not "amend her complaint to avoid preemption"); *Chae v. SLM Corp.*, 593 F.3d 936, 943 (9th Cir. 2010) ("[P]reemption cannot be avoided simply by relabeling an otherwise-preempted claim."). As the Court finds that Eisman's claims are preempted by 21 U.S.C. § 379r because Eisman's theories of liability are fundamentally at odds with the FDA's conclusions about the safety and effectiveness of OTC Coal Tar drug products, the Court concludes amendment would be futile. Accordingly, the Court declines to grant leave to amend.

V. CONCLUSION

For the reasons discussed above, the Court **GRANTS** Defendants' Motion to Dismiss with prejudice. (ECF No. 18.)

IT IS SO ORDERED.

January 17, 2025



OTIS D. WRIGHT, II
UNITED STATES DISTRICT JUDGE